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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,531	01/11/2002	Jeanne Maruani	IVD978-2	4927

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EXAMINER
KIM, JENNIFER M

ART UNIT	PAPER NUMBER
1617	5

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/044,531	Applicant(s) MARUANI ET AL.	
	Examin r Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-33 and 39* is/are pending in the application.

4a) Of the above claim(s) *30-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-29 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/341,764* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group I, claims 19-29 and 39, claims drawn to a pharmaceutical composition in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the claims are not drawn to a same inventive concept and should, therefore, be considered a single invention and not "two or more independent and distinct inventions" within the meaning of 35 U.S.C. 121. This is not found persuasive because the claims are drawn to a independent and distinct inventions since they have acquired a separate status in the art as shown by the different classification therefore the required non-patent literature search would place burden on the Examiner. Therefore, the restriction requirement set forth in last Office Action is deemed proper.

Accordingly, claims 30-33 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-23, 26-29 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barth et al. (U.S.Patent No. 5624941) and Baroni et al. (U.S.Patent No. 5488151).

Barth et al. teach Applicants active agent, CB_1 receptor antagonist set forth in claims 19,21 and 39 useful for the treatment of glaucoma. (abstract, column 2, column 88, claim 27). Barth et al. also teach the dosage range of the CB_1 receptor antagonist within the Applicants' range set forth in claims 27-29. (column 27, lines 10-35).

Baroni et al. teach Applicants active agent, β_3 agonist set forth in claims 19, 23 and 26 useful for the treatment of glaucoma. (abstract, columns 1 and 2, column 2, lines 32-35, column 4, claim 1). Baroni et al. also teach the dosage range of the β_3 agonist within the Applicants' range set forth in claims 27-29. (column 3, line 63 – column 4, line 11).

The claims differ from the cited references in claiming combination of CB1 receptor antagonist, and β_3 agonist, to treat glaucoma. To employ combinations of CB1 receptor antagonist and β_3 agonist to treat glaucoma would have been obvious because all the components are well known individually for treating glaucoma. It would be expected that the combination of components would treat glaucoma as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Therefore, it would have been prima facie obvious to combine CB_1 receptor antagonist, and β_3 agonist composition cojointly in a formulation to treat glaucoma.

Claims 19-22, 24 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Barth et al. (U.S.Patent No. 5624941) and Brazzell et al. (U.S.Patent No. 5578638).

Barth et al. teach Applicants active agent, CB_1 receptor antagonist set forth in claims 19 and 21 useful for the treatment of glaucoma. (abstract, column 2, column 88, claim 27).

Brazzell et al. teach β_3 agonist (formula IV) useful for the treatment of glaucoma. (abstract, column 1. lines 7-15, columns 3-7).

The claims differ from the cited references in claiming combination of CB_1 receptor antagonist, and β_3 agonist, to treat glaucoma. To employ combinations of CB1 receptor antagonist and β_3 agonist to treat glaucoma would have been obvious because all the components are well known individually for treating glaucoma. It would be expected that the combination of components would treat glaucoma as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Therefore, it would have been prima facie obvious to combine CB_1 receptor antagonist, and β_3 agonist composition cojointly in a formulation to treat glaucoma.

Claims 19-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barth et al. (U.S.Patent No. 5624941) and Cecchi et al. (U.S.Patent No. 5130339).

Barth et al. teach Applicants active agent, CB_1 receptor antagonist set forth in claims 19 and 21 useful for the treatment of glaucoma. (abstract, column 2, column 88, claim 27).

Cecchi et al. teach β_3 agonist (formula V) useful for the treatment of glaucoma. (Abstract, column 1, line 38 – column 2, line 21, column 17, lines 4-12).

The claims differ from the cited references in claiming combination of CB1 receptor antagonist, and β_3 agonist, to treat glaucoma. To employ combinations of CB1 receptor antagonist and β_3 agonist to treat glaucoma would have been obvious because all the components are well known individually for treating glaucoma. It would

be expected that the combination of components would treat glaucoma as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Therefore, it would have been prima facie obvious to combine CB_1 receptor antagonist, and β_3 agonist composition cojointly in a formulation to treat glaucoma.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
June 11, 2003